K012743

SEP 1 4 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
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Marie L. Holm, Associate Product Regulations Manager, Regulatory Affairs

DEVICE NAME

Trillium™ Tri-optic Measurement Cell

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

Tri-optic Measurement Cell (K910421)
AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

DESCRIPTION OF DEVICE

The Trillium™ Tri-optic Measurement Cell is a single-use insert designed to be used in the BioTrend Oxygen Saturation and Hematocrit System (K954501). The BioTrend Oxygen Saturation and Hematocrit System measures oxygen saturation and hematocrit by using dual wavelength photometric techniques. The Tri-optic Measurement Cell is an in-line, full flow, sterile and non-pyrogenic fluid path disposable device. The device accommodates the transmission of the light-emitting signal into the blood path and collection of the backscattered light signal.

STATEMENT OF INTENDED USE

The Trillium™ Tri-optic Measurement Cell is to be used with the BioTrend Oxygen Saturation and Hematocrit System.

The BioTrend Oxygen Saturation and Hematocrit System measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed chest support and limb perfusion

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The Tri-optic Measurement Cell is to be used with the BioTrend Oxygen Saturation and Hematocrit System.

The BioTrend Oxygen Saturation and Hematocrit System measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed chest support and limb perfusion

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the Tri-optic Measurement Cell. The modification to the current Tri-optic Measurement Cell is to coat the blood contact surfaces with Trillium™.

The Trillium™ Tri-optic Measurement Cell is being compared to the following marketed devices:

- Tri-optic Measurement Cell (K910421)
- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

The Trillium™ Tri-optic Measurement Cell has the same indications statement and intended uses as the:

- Tri-optic Measurement Cell (K910421)

The Trillium™ Tri-optic Measurement Cell has "no new technological characteristics (e.g., materials and manufacturing processes)" from the Tri-optic Measurement Cell. The technological characteristic is solely the coating material of the blood pathway:

- Trillium™

The technological characteristic of the Trillium™ Biopassive Surface is common to other medical devices (hollow fiber oxygenators) currently in commercial distribution as follows:

- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the Trillium™ Tri-optic Measurement Cell is substantially equivalent to other marketed extracorporeal cardiopulmonary bypass devices.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Trillium™ Tri-optic Measurement Cell does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed extracorporeal cardiopulmonary devices.

The *in vitro* bench testing included analysis of:

Coating Characteristics

Physical Characteristics

Performance Characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

Ms. Marie L. Holm
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K012743
Trade Name: Trillium™ Tri-optic Measurement Cell (TMC 25T, 38T, and 50T)
Regulation Number: 21 CFR 870.4330
Regulation Name: Monitor, blood gas, on-line, cardiopulmonary bypass
Regulatory Class: Class II (two)
Product Code: DRY
Dated: August 15, 2001
Received: August 16, 2001

Dear Ms. Holm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number if known: K012743

Device Name: Trillium™ Tri-optic Measurement Cell

The Trillium™ Tri-optic Measurement Cell is intended for use in the BioTrend oxygen saturation and hematocrit system.

Indications for Use:

The BioTrend oxygen saturation and hematocrit system measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed chest support and limb perfusion.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012743

Prescription Use ✓ OR Over-The-Counter use ____
(Per 21 CFR 801.109)